

# Exhibit 33

Beverly Winikoff, et al., *Extending Outpatient Medical Abortion Services Through 70 Days of Gestational Age*, 120 *Obstetrics & Gynecology* 1070 (2012)

# Extending Outpatient Medical Abortion Services Through 70 Days of Gestational Age

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**OBJECTIVE:** To estimate the efficacy and acceptability of medical abortion at 64–70 days from last menstrual period (LMP) and to compare it with the already proven 57–63 days from LMP gestational age range.

**METHODS:** This prospective, comparative, open-label trial enrolled 729 women with pregnancies 57–70 days from LMP requesting abortion at six U.S. clinics. Medical abortions were managed with 200 mg mifepristone and 800 micrograms buccal misoprostol and sites' service delivery protocols. Follow-up visits occurred 7–14 days after mifepristone, with an abortion considered complete if surgical intervention was not performed. Success, ongoing pregnancy, and acceptability rates were compared.

**RESULTS:** A total of 629 cases were analyzable for efficacy. Success rates were similar in the two groups (57–63 days group: 93.5%, 95% confidence interval [CI] 90–96; 64–70 days group: 92.8%, 95% CI 89–95). Ongoing

pregnancy rates also did not differ significantly (57–63 days: 3.1%, 95% CI 1.6–5.8; 64–70 days: 3.0%, 95% CI 1.5–5.7). Acceptability was high and similar in both arms, with most women (57–63 days: 87.4%; 64–70 days: 88.3%) reporting that their experience was either very satisfactory or satisfactory.

**CONCLUSION:** Medical abortion with mifepristone and misoprostol in current outpatient settings is an efficacious and acceptable method of ending pregnancies 64–70 days from LMP and can be offered without alteration of existing services.

**CLINICAL TRIAL REGISTRATION:** ClinicalTrials.gov, www.clinicaltrials.gov, NCT00997347.

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**LEVEL OF EVIDENCE: II**

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*The findings and conclusions in this article are those of the authors and do not necessarily represent the views of Planned Parenthood Federation of America.*

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When medical abortion with mifepristone and misoprostol was approved by the U.S. Food and Drug Administration (FDA) in 2000, the regimen was recommended for outpatient use through 49 days from the last menstrual period (LMP).<sup>1</sup> Extensive research and more than 11 years of experience in the United States with approximately 1.75 million uses have established that medical abortion is safe and effective through 63 days from LMP when used by women at home (May 2011, Danco Laboratories, personal communication).<sup>2–6</sup>

Generally, women in the United States whose first-trimester pregnancies are beyond 63 days from LMP are not offered medical abortion with mifepristone and misoprostol. Medical abortion after 63 days from LMP is occasionally available outside the United States, but only on an inpatient basis using complex regimens.<sup>7–9</sup> Inpatient protocols typically involve re-dosing of medications, vaginal speculum examination, and an overnight stay, and are burdensome for women, providers, and health care systems. Data supporting use of medical abortion past 63 days from



LMP in outpatient services are limited to one small trial, but results were not available when this study began.<sup>10</sup> Our study sought to estimate the efficacy and acceptability of the most common outpatient medical abortion regimen in the United States (200 mg mifepristone and 800 micrograms buccal misoprostol) through 70 days from LMP and to compare outcomes between women with pregnancies of 64–70 days' duration and women with pregnancies in the range of 57–63 days. The gestational age limit of 70 days extends the usual gestational age cutoff of 63 days by 1 week.

## MATERIALS AND METHODS

The study was performed at six facilities: Family Planning Associates Medical Group (Chicago, IL), Planned Parenthood League of Massachusetts (Boston, MA), Planned Parenthood of New York City (New York, NY), Planned Parenthood of Waco (Waco, TX), Presidential Women's Center (West Palm Beach, FL), and Planned Parenthood of Minnesota, North Dakota, South Dakota (St. Paul, MN). The Quorum Review Institutional Review Board approved the protocol.

Women seeking pregnancy termination were invited to participate in the study if they were eligible for medical abortion, were at least 18 years old, and had a confirmed intrauterine pregnancy 57 through 70 days from LMP, based on routine ultrasound practices of the respective study sites (crown-rump length+42 was most commonly used). Participants had to be willing and able to provide informed consent, have access to a telephone and emergency transportation, be able to speak and read English or Spanish, and agree to follow study protocols. Screening and enrollment generally occurred during the same visit, except when a state-mandated 24-hour waiting period after informed consent required a second visit.

On day 1, participants swallowed mifepristone 200 mg (Mifeprex) in the clinic and then were provided with misoprostol 800 micrograms to take 24–48 hours later at home. Women were instructed to hold the misoprostol buccally for 30 minutes before swallowing any remains. Analgesics and anti-nausea medications were dispensed or prescribed according to local standards at each facility, and participants were counseled to call the clinic with questions or concerns. Participants maintained a diary for up to 15 days to record time of misoprostol administration, bleeding, expulsion time (if recognized), pain medications used, and days of missed work or school.

Participants returned to the study site 7 to 14 days after using mifepristone (according to clinic practice) for clinical assessment, which included ultrasonography. Uterine suction curettage was recommended for women with ongoing pregnancies. Women with nonviable pregnancies (eg, empty sac or static size with absent cardiac activity on ultrasonography) could opt for suction curettage, expectant management, or a second misoprostol dose. If either of the latter two options was chosen, then women were asked to return to the clinic in 1 week for further follow-up. If a persistent nonviable pregnancy was diagnosed at the extended follow-up visit, suction curettage was recommended. Providers also intervened surgically if they deemed it medically necessary or at the patient's request. After expulsion of uterine contents was confirmed, women responded to a semi-structured interview about their experiences with the medical abortion overall, the incidence of side effects and their severity (based on their own definitions of mild, moderate, and severe), and the acceptability of the procedure. If a participant failed to return for a follow-up visit, then assessment of abortion status and the interview could be conducted by telephone. Study sites were required to document at least three attempts to contact women who were lost to follow-up.

The study's primary objective was to assure that an outpatient medical abortion regimen could be used in gestations 64–70 days from LMP and achieve a success rate of at least 90%, which would characterize a clinically acceptable regimen. A cohort of women with gestations 57–63 days from LMP was also enrolled to serve as a comparison; 334 women per group were needed to detect a 5% or greater lower efficacy than the hypothesized 95% success rate in the 57–63 days group, based on previously published reports ( $\alpha=0.05$ ,  $1-\beta=0.8$ , using a one-tailed test) and would allow us to estimate a success rate of 90% with a confidence interval (CI) of  $\pm 3.2\%$ .<sup>2–3,11</sup> Data were analyzed using SPSS 15.0. An independent data and safety monitoring committee reviewed the interim results for safety and efficacy after 50% of the data were available.

The primary outcome of the trial was complete abortion without surgical intervention at any point, regardless of the number of misoprostol doses used. Secondary outcomes included side effects, patient satisfaction and acceptability, days of heavy bleeding, days of missed work or school, and number of calls and unscheduled visits to the clinic. One-tailed  $P<.05$  was considered to indicate statistical significance. We chose to use one-tailed  $P$  values because our objective was to determine whether use of medical abortion in



the gestational age range of 64–70 days would result in worse outcomes than its current use in the 57- to 63-day age range. Binomial proportion CIs for efficacy rates were calculated. We used Fisher's exact test to determine differences in proportions, and for continuous variables we used the Student *t* test to determine differences in means.

## RESULTS

Between August 2009 and February 2011, the study sites enrolled 729 women; 379 women in the 57–63 days group and 350 women in the 64–70 days group. Fifty-three (14%) women in the earlier and 45 (13%) in the later gestational age group were lost to follow-up, and two women, one from each group, withdrew before using mifepristone. Enrollment was continued to 729 women to compensate for loss to follow-up. Six-hundred twenty-nine cases had outcome data, short of the estimated sample size of 668. Analysis of the outcomes at that time were conducted to determine the utility of continuing the study and whether a statistically significant difference in success would be possible if the study were to continue and the remaining 39 analyzable case records were available. We analyzed the hypothetical scenario that maximized the possible difference in efficacy between the two groups by adding all 39 hypothetical additional cases to the 57–63 days group (because it had the higher efficacy rate) and assuming that every woman had a successful abortion (to model the maximum mathematical differences possible between the groups). This model improved the efficacy rate in the 57–63 days study group by 0.7 percentage points and doubled the difference in efficacy between the two gestational age groups from 0.7% to 1.4%. Comparing the projected success rates of the two gestational age groups resulted in  $P=0.2$ . It was therefore determined that enrolling all 688 women would not show a statistically significant or a clinically meaningful difference in success

rates. The study would have required an additional 13,120 women with follow-up in each study group (total 26,240 analyzable cases) to be able to find a statistically significant difference between the observed success rates. Therefore, a total of 629 medical abortions, 325 in the 57–63 days group and 304 in the 64–70 days group, were analyzed for efficacy in the final analysis. Baseline characteristics of women in the two groups were similar for mean age, education level, gravidity, and previous abortions (Table 1).

Efficacy of the outpatient medical abortion regimen in the 57–63 days group was 93.5% (95% CI 90.1–95.9) and 92.8% (95% CI 89.1–95.3;  $P=.41$ ) in the 64–70 days group (Table 2). Three percent of women in both groups had a surgical intervention because of ongoing pregnancy (57–63 days: 3.1%, 95% CI 1.6–5.8; 64–70 days: 3.0%, 95% CI 1.5–5.7;  $P=.62$ ). Rates of surgical intervention attributable to persistent nonviable pregnancy or sac ( $P=.33$ ), substantial uterine debris ( $P=.29$ ), excessive prolonged bleeding ( $P=.75$ ), or woman's request ( $P=.86$ ) were comparable between study groups. There was no significant difference in efficacy by study site ( $P=.137$ ).

Approximately 5.2% of women in the 57–63 days group and 5.3% of women in the 64–70 days group had incomplete abortion diagnosed (ie, persistent gestational sac or substantial debris) at their first follow-up visits ( $P=.56$ ). The majority were treated with a second dose of misoprostol, with those in the 57–63 days group receiving a second dose at a higher rate than those in the 64–70 days group (76.5% compared with 56.3%;  $P=.195$ ). Of those who received a second dose of misoprostol and underwent an extended follow-up evaluation, 91% (10 of 11) in the earlier and 66.7% (6 of 9) in the later gestational age group were determined to have a complete abortion ( $P=.974$ ).

Almost 70% of participants in each group reported a time of expulsion at follow-up. Among women who reported a time of expulsion, those in

**Table 1. Participant Demographic Characteristics**

	57–63 d (n=325)	64–70 d (n=304)	<i>P</i> (Two-Tailed)
Age (y)	26 (18–42)	26 (18–42)	.66
Primigravid woman	32 (103)	31 (94)	.86
Previous abortion	47 (154)	48 (146)	.87
Previous medical abortion	21 (67)	24 (72)	.39
Education level	322	303	4 unknowns
Less than high school	8 (24)	9 (26)	.71
High school	59 (191)	60 (183)	.85
University	27 (87)	27 (83)	.99
Postgraduate	6 (20)	4 (11)	.19

Data are mean (range), n (%), or n unless otherwise specified.

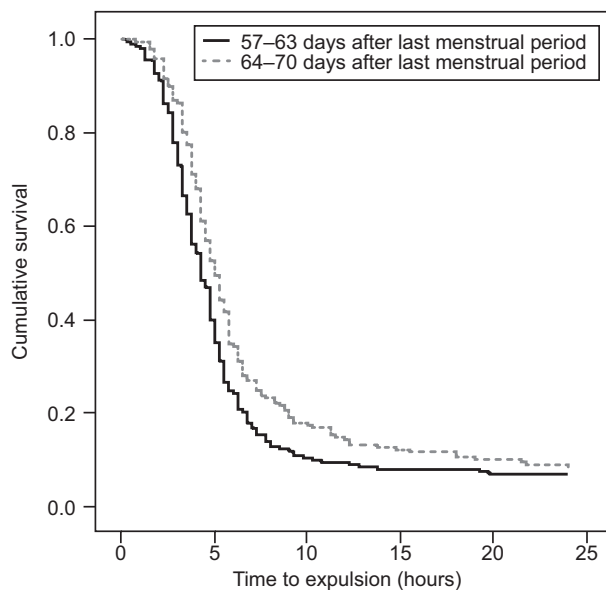


**Table 2. Efficacy and Major Adverse Events by Gestational Age Group**

	57–63 d (n=325)	64–70 d (n=304)	P (One-Sided)
Success	93.5 (304; 90–96)	92.8 (282; 89–95)	.41
Interventions	6.5 (21)	7.2 (22)	
Ongoing pregnancies	3.1 (10)	3.0 (9)	.62
Persistent nonviable sac	0.92 (3)	1.6 (5)	.33
Substantial debris in uterus	0.31 (1)	1.0 (3)	.29
Excessive prolonged bleeding	1.2 (4)	1.0 (3)	.75
Woman's request	0.61 (2)	0.33 (1)	.86
Other	0.31 (1)	0.33 (1)	.73
Major adverse events			
Went to emergency department	3.7 (12)	4.6 (14)	.36
Received blood transfusion	0.6 (2)	0.3 (1)	.52
Admitted to hospital	0.9 (3)	0.7 (2)	.53

Data are % (n; 95% confidence interval) or % (n) unless otherwise specified.

the earlier gestational age group were significantly more likely than those in the later gestational age group to expel sooner (Fig. 1; log-rank test  $P=.005$ ). This difference in reported expulsion time was most notably seen at 3 hours after using misoprostol (37.7% in week 9 compared with 22.5% in week 10;  $P=.001$ ), but equal numbers (93.1% compared with 92.1%, respectively;  $P=.43$ ) reported expulsion by 24 hours (Fig. 1).



**Fig. 1.** Time from misoprostol administration to pregnancy expulsion. Survival curves of the number of hours since misoprostol administration until pregnancy expulsion for women 57–63 days from last menstrual period or 64–70 days from last menstrual period. Includes women who reported a time of expulsion, excluding those with ongoing pregnancies or persistent nonviable sac at follow-up. Log-rank test  $P=.005$ .

Winikoff. Medical Abortion Through 70 Days From LMP. *Obstet Gynecol* 2012.

Twenty-nine women made visits to an emergency department, primarily for pain and bleeding during the study period (3.7% from the earlier gestational age group and 4.6% from the later group ( $P=.35$ )) (Table 2). Three women received blood transfusions, two in the 57–63 days group and one in the 64–70 days group ( $P=.52$ ). One woman in the 57–63 days group was admitted to the hospital and was successfully treated for *Escherichia coli* sepsis, and one woman in the 57–63 days group with a history of chronic pancreatitis was admitted to the hospital for recurrence of her disease.

Eighty-five percent of participants completed and submitted the diaries they maintained for up to 15 days. Mean duration of heavy bleeding did not differ significantly by group (Table 3). There was no significant difference in mean days of work or school missed by women because of the abortion (1.85 in 57–63 days group compared with 1.80 in 64–70 days group;  $P=.81$ ).

The side effect profiles of each study group were similar, with no significant differences except for vomiting (Table 3). A minority of women in each group experienced this side effect, but fewer in the earlier gestational age group (36% compared with 46%;  $P=.01$ ). However, severe vomiting was no different in the two groups (10.7% for 57–63 days compared with 12.0% for 64–70 days;  $P=.35$ ). Opiates were reportedly used more often for pain relief by women in the 64–70 days group (76% in the 57–63 days group compared with 84%;  $P=.003$ ), but nonsteroidal anti-inflammatory drug use did not differ. Mean days of any analgesic use were the same in both groups. Fewer women in the 57–63 days group reported use of anti-emetic medication (34% compared with 46%;  $P=.002$ ). The study participants requested relatively little clinic staff time beyond the scheduled study visits. Only 20%





**Table 3. Side Effect and Bleeding Profile**

Side Effects	57–63 d (n=318)	64–70 d (n=300)	P (One-Sided)
None	22.6 (72)	17.0 (51)	.05
Chills	24.2 (77)	22.7 (68)	.36
Fever	11.9 (38)	10.3 (31)	.31
Vomiting	35.8 (114)	45.7 (137)	.008
Nausea	50.0 (159)	51.7 (155)	.37
Diarrhea	17.9 (57)	17.3 (52)	.47
Heavy bleeding	319	298	
Days of heavy bleeding	2.5±2.06 (0–14)	2.3±1.86 (0–11)	.09
Median days of heavy bleeding	2	2	

Data are % (n), n, or mean±standard deviation (range) unless otherwise specified.

of women in both groups made phone calls because of concerns related to their abortion, and 4% of women in the earlier and 3% of women in the later gestational age groups made unanticipated clinic visits.

The majority of women in both groups (57–63 days: 87.4%; 64–70 days: 88.3%) reported being either satisfied or very satisfied with the medical abortion method, and 78% and 79% of women in the two groups, respectively, reported that they would choose medical abortion again instead of surgery. Women in the earlier gestational age group were as likely to report seeing the pregnancy or some part of it as those in the later gestational age group (64% compared with 69.3%;  $P=.10$ ). There were no significant differences in women's reported reactions to what they saw, with the exception that women in the earlier gestational age group were more likely to report "nothing or no feeling" (13.9% compared with 8.2%;  $P=.04$ ) and those in the later group were more likely to report that they were "relieved" (7.4% compared with 13.9%;  $P=.02$ ).

## DISCUSSION

The results show that medical abortion with an outpatient regimen of 200 mg mifepristone followed 24 to 48 hours later by 800 micrograms buccal misoprostol self-administered at home is efficacious and acceptable in women 64 to 70 days from LMP and is not statistically or clinically different from a current outpatient medical abortion protocol used with women 57–63 days from LMP. In 2000, the FDA approved mifepristone based on an efficacy of 92% for gestations up to 49 days from LMP.<sup>12</sup> The success rate achieved in this study during week 10 of gestation (92.8%) is similar to that rate and clinically acceptable. Based on this evidence, medical abortion using the study protocol can be extended from 63 days from LMP to 70 days from LMP without reconfiguration of existing outpatient clinical services. Our findings are consistent with those of Boersma et al,<sup>10</sup> who

offered the same outpatient medical abortion regimen as in the current study to 26 women with gestational ages 64–70 days from LMP, but with an interval of 24–36 hours between the mifepristone and misoprostol doses. That study found 96% success in those women but was too small to provide reliable point estimates of success rates.

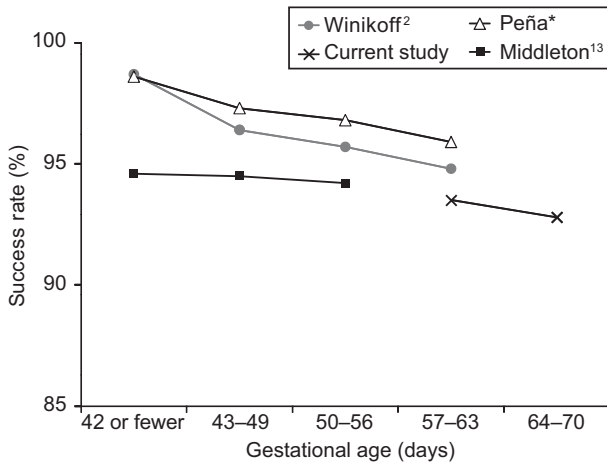
The study cannot reject the null hypothesis that there is no difference between the success rates of medical abortion among women with pregnancies of 9 and 10 weeks of gestation. Although the inability to reject the null hypothesis theoretically could be attributable to early cessation of the study, the observed differences between study groups are much smaller than those originally hypothesized and are not clinically meaningful. The additional analyses conducted also suggest that continuing enrollment to include 668 analyzable cases would not have affected the study conclusions.

The overall high efficacy of the medical abortion regimen used in this study through 63 days from LMP is well-documented, and only a very minimal decline in efficacy as gestational age increases has been noted.<sup>2,13</sup> The trend observed in the two point estimates for success in weeks 9 and 10 in this study is consistent with such a small decline (Fig. 2), alleviating concern of an abrupt decline in efficacy of the method beyond 63 days from LMP.

The study was not powered to detect a difference in safety outcomes because major adverse events attributable to medical abortion (eg, hospitalizations, emergency department visits, and blood transfusions) are rare. No medical abortion studies (including the pilot studies on which FDA approval was based) were powered to detect rates of rare occurrences such as transfusion or hospitalization. Similar to those studies, the occurrence of major adverse events in this study was very infrequent.

Many studies have explored women's experiences with outpatient medical abortion in the first trimester,<sup>14</sup>





**Fig. 2.** Efficacy of mifepristone medical abortion with 800 micrograms buccal misoprostol from 49 to 70 days from last menstrual period. Illustration of success rates by gestational age from different studies that used the same medical abortion regimen as in this study. \*Peña M. Medicamentos para la interrupción legal del embarazo: La experiencia de la Secretaría de Salud del Distrito Federal (Mexico). 20th Congress of the Latin American Federation of Obstetrics and Gynecology (FLASOG) 2011; Managua, Nicaragua.

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but often the information is not disaggregated by week. Although our findings do not show any differences between the two study groups in such aspects as bleeding profiles, days of school or work missed, and reports of seeing the expulsion, women's experiences at these later weeks of gestational age may differ in some ways from women with earlier first-trimester pregnancies. The results from this study may help clinicians who provide medical abortion to women with pregnancies 57–70 days of gestational age to tailor counseling messages to prepare women for what to expect. For example, more than two-thirds of women reported witnessing uterine expulsion, so women should be counseled on that likelihood. Women with gestations in week 10 may expel their pregnancies less quickly after using misoprostol, but perhaps this is not surprising given the slightly larger size of the gestational sac at the later gestational age. The fact that more women in week 10 expressed relief after their medical abortions could be an artifact of participating in the test group of a research trial.

Some women may have been misclassified into study groups based on usual variability in gestational age dating by ultrasonography. To be sure that such misclassification would not have affected study results, reanalysis of success among women with pregnancies at the opposite extremes of the gestational age

spectrum considered in this study (ie, a comparison of the earlier half of the early age range with the latter half of the later age range), as well as by standardizing gestational age assessment, did not affect our outcomes or our conclusions (data not shown).

The content of counseling was not dictated by the study protocol and was based on usual counseling provided. Possible assumptions that pain, bleeding, and the size of the expelled fetus in week 10 may be more than at earlier weeks of gestation could have had an effect on women's perceptions. It is also possible that there were slight differences in counseling messages as a result of the counselors' knowledge of gestational age in each woman. Similarly, observations and experience amassed during the course of the study may have resulted in adjustments in counseling messages to later enrollees, better-preparing women with pregnancies in week 10 for what they might experience.

The study sites already were highly experienced at providing medical abortion and were accustomed to administering the specific regimen used in this study. Therefore, the observed efficacy rates may not be generalizable to clinics that are less experienced. Results also are not generalizable to regimens other than the one studied, for either efficacy or the side effects of misoprostol, which are known to vary by route and dose. Last, because adverse events were so rare in our study, the sample size was not sufficient to characterize adequately the occurrence of adverse events for women who terminate their pregnancies medically during the ninth or tenth week other than to say that serious events are infrequent and side effects are tolerable.

In conclusion, the regimen of 200 mg mifepristone and 800 micrograms buccal misoprostol is efficacious and acceptable for women seeking medical abortion with pregnancies of 70 days or less. The findings of this research are important for expanding the availability of this nonsurgical option to women seeking termination of pregnancy in the first trimester.

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